

CHAPTER II

09/701948

**TRANSMITTAL LETTER
TO THE UNITED STATES ELECTED OFFICE (EO/US)
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)**

<u>PCT/GB99/01756</u>	<u>04 JUNE 1999</u>	<u>05 JUNE 1998</u>
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
<u>FLEXIBLE SHEET MATERIAL AND METHOD OF MAKING SAME</u>		
TITLE OF INVENTION		
<u>JO McKNIGHT and SHAUN AMBROSE-JONES</u>		
APPLICANT(S)		

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231

ATTENTION: EO/US

NOTE: *The completion of those filing requirements that can be made at a time later than 30 months from the priority date results from the Commissioner exercising his judgment under the authority granted under 35 USC 371(o). The filing receipt will show the actual date of receipt of the last item completing the entry into the national phase. See 37 CFR 1.491 which states: 'An international application enters the national state when the applicant has filed the documents and fees required by 35 USC 371(c) within the periods set forth in § 1.494 and § 1.495.'*

WARNING: *Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 CFR 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing - See 37 CFR 1.8.*

NOTE: *Documents and fees must be clearly identified as a submission to enter the national state under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111. 37 CFR 1.494(f).*

CERTIFICATION UNDER 37 C.F.R. 1.10

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date 05 DECEMBER 2000, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number FL57487435305, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Judith Biebel

(Type or print name of person mailing paper)

(Signature of person mailing paper)

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

WARNING: *Each paper or fee filed by 'Express Mail' must have the number of the 'Express Mail' mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b). 'Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition. " Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

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1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

- a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).
- b. ☒ The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 CFR 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCU- LATIONS
	TOTAL CLAIMS	39 -20	19	X 18.00	\$342.00
	INDEPENDENT CLAIMS	2 -3	0	X80.00	\$
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)				\$270.00
BASIC FEE	<input type="checkbox"/> US PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in §1.482 has been paid on the international application to the US PTO: <input type="checkbox"/> and the international preliminary examination reports states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 CFR 1.492(a)(4)). \$96.00 <input type="checkbox"/> and the above requirements are not met (37 CFR 1.492(a)(1)) \$670.00 <input checked="" type="checkbox"/> US PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in §1.482 has been paid to the USPTO, and payment of an international search fee as set forth in §1.445(a)(2) to the USPTO: <input type="checkbox"/> has been paid (37 CFR 1.492(a)(2)) \$690.00 <input type="checkbox"/> has not been paid (37 CFR 1.492(a)(3)) \$970.00 <input checked="" type="checkbox"/> where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 CFR 1.492(a)(5)) \$840.00				\$840.00
	Total of above Calculations				1452.00
SMALL ENTITY	Reduction by ½ for filing by small entity, if applicable. Affidavit must be filed also (Note 37 CFR 1.9, 1.27, 1.28)				-0
	Subtotal				\$1452.00
	Total National Fee				\$1452.00
	Fee for recording the enclosed assignment document (37 CFR 1.21(h)). See Item 13 below). See attached "ASSIGNMENT COVER SHEET". \$40.00				
TOTAL	TOTAL FEES ENCLOSED				\$1452.00

- i. ☐ A check in the amount of 1452.00 to cover the above fees is enclosed.
- ii. ☐ Please charge Account No. 06-2360 in the amount of \$ 130.00
(Surcharge for filing Declaration/Power of Attorney)
A duplicate copy of this sheet is enclosed.

WARNING: To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 CFR § 1.495(b).

WARNING: If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 CFR § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.

3. ☐ A copy of the International application as filed (35 U.S.C. 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. 'The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47. 1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date.' Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

- a. ☐ is transmitted herewith.
- b. ☐ is not required, as the application was filed with the United States Receiving Office.
- c. ☒ has been transmitted
- i. ☒ by the International Bureau.
Date of mailing of the application (from form PCT/IB/308): 16
December 1999 (copy attached)
- ii. ☐ by applicant on _____
Date

4. ☐ A translation of the International application into the English language (35 U.S.C. 371(c)(2)):

- a. ☐ is transmitted herewith.
- b. ☒ is not required as the application was filed in English.
- c. ☐ was previously transmitted by applicant on _____
Date
- d. ☐ will follow.

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5. ☒ Amendments to the claims of the International application under PCT Article 19 (38 U.S.C. 371 (c)(3)):

NOTE The Notice of January 7, 1993 points out that 37 CFR § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that, 'The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected.' 1147 O.G. 29-40, at 36.

- a. ☐ are transmitted herewith.
- b. ☐ have been transmitted
- i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1 B/308): _____
- ii. ☐ by applicant on _____
- c. ☒ have not been transmitted as
- i. ☒ applicant chose not to make amendments under PCT Article 19. Date of mailing of Search Report (from form PCT/ISA/210.): 06 September 1999
- ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.
6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):
- a. ☐ is transmitted herewith.
- b. ☐ is not required as the amendments were made in the English language.
- c. ☒ has not been transmitted for reasons indicated at point 5(c) above.
7. ☒ A copy of the international examination report (PCT/IPEA/409)
- ☒ will be furnished upon its receipt.
- ☐ is not required as the application was filed with the United States Receiving Office.
8. ☒ Annex(es) to the international preliminary examination report
- a. ☒ will be transmitted upon their receipt, if appropriate.
- b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report
- a. ☒ will be transmitted upon their receipt, if appropriate.
- b. ☐ is not required as the annexes are in the English language.
10. ☒ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115
- a. ☐ was previously submitted by applicant on _____
Date
- b. ☐ is submitted herewith, and such oath or declaration
- i. ☐ is attached to the application.
- ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. 1.70.
- c. ☒ will follow.

OTHER DOCUMENT(S) OR INFORMATION INCLUDED:

11. ☒ An International Search Report (PCT/ISA/21 0) or Declaration under PCT Article 17(2)(a):
- a. ☒ is transmitted herewith.
- b. ☐ has been transmitted by the International Bureau. Date of mailing (from form PCT/IB/308):
- c. ☐ is not required, as the application was searched by the United States International Searching Authority.
- d. ☐ will be transmitted promptly upon request.
- e. ☐ has been submitted by applicant on _____
Date

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12. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98:
- a. ☐ is transmitted herewith.
Also transmitted herewith is/are:
☐ Form PTO-1449 (PTO/SB/08A and 08B).
☐ Copies of citations listed.
- b. ☒ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).
- c. ☐ was previously submitted by applicant on _____
Date
13. ☒ An assignment document is transmitted herewith for recording.
A separate "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" will follow.
14. ☒ Additional documents:
- a. ☒ Copy of request (PCT/RO/101)
- b. ☒ International Publication No. WO 99/64238
- i. ☒ Specification, claims and drawing
- ii. ☐ Front page only
- c. ☒ Preliminary amendment (37 C.F.R. § 1.121)
- d. ☒ Other
Copy of Request, Demand and Written Opinion are enclosed.

15. ☒ The above checked items are being transmitted
- a. ☒ before 30 months from any claimed priority date.
- b. ☐ after 30 months.
16. Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on _____
namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.*

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 06-2360.

☒ 37 C.F.R. 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 CFR § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☒ 37 C.F.R. 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. 1.17 (application processing fees)

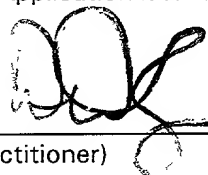
WARNING: *While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." Notice of Nov. 5, 1985 (1060 O.G. 27).*

☐ 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))

NOTE: *Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).*

NOTE: *37 C.F.R. 1.28(b) requires 'Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee.' From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.*

☒ 37 CFR 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).



(Signature of Practitioner)

Daniel D. Ryan

(Type or Print Name of Practitioner)

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MILWAUKEE, WISCONSIN 53226

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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : McKnight et al. Examiner: Unknown
Serial No. : Unknown Group Art Unit: Unknown
Filed : Unknown
For : Flexible Sheet Material and Method of Making Same

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PRELIMINARY AMENDMENT
ACCOMPANYING NATIONAL PHASE ENTRY REQUEST
OF PCT/GB99/01756

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Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Please amend this application prior to calculation of the filing fees, as follows:

IN THE CLAIMS:

Please cancel claim 5-20.

Please consider the following new claims 21 to 35

21 (New). A sheet material according to claim 1 or 2 or 3 or 4 wherein the first layer is a textile fabric.

22 (New). A sheet material according to claim 21 wherein the second layer is a polyurethane composition.

23 (New). A sheet material according to claim 21 wherein the selected part comprises a first region and a second region and wherein the perforations are of different dimensions in the first region from those in the second region.

23 (New). A sheet material according to claim 21 wherein the perforations in the first region are larger than those in the second region.

24 (New). A sheet material according to claim 21 wherein the perforations in the first and second region each have a diameter between 0.1 mm and 1.6 mm.

25 (New). A sheet material according to claim 21 wherein the first region extends lengthwise along a central part of the sheet material and the second region extends lengthwise at either side of the central part.

26 (New) A sheet material according to claim 1 wherein the third layer is a polyurethane composition.

27 (New). A sheet material according to claim 1 wherein one or more longitudinally extending ducts are provided between the second and third layers for ducting air under pressure to the first layer.

28 (New). A sheet material according to claim 1 comprising one or more openings in the second layer through which air under pressure can be supplied to the first layer.

29 (New). A method of making a laminated sheet material comprising:

- (a) procuring an air permeable first layer;
- (b) laminating to one face of the first layer, an air-impermeable second layer comprising a material of uniform thickness;
- (c) laminating to the face of the first layer opposite to the face carrying the second layer, an air-impermeable third layer of uniform thickness; and
- (d) forming a set of perforations through the second layer at a selected part thereof.

30 (New). A method according to claim 29 wherein the first layer is a textile fabric.

31 (New). A method according to claim 29 or 30 wherein the second layer is a polyurethane composition.

32 (New). A method according to claim 31 wherein the perforations are made by perforating the second layer after the first and second layers have been laminated to one another.

33 (New). A method according to claim 32 wherein the perforations in a first region of the selected part are of different dimensions from those in a second region.

34 (New). A method according to claim 33 wherein the second layer is laminated with the first layer by transfer-coating.

35 (New). A method according to claim 34 wherein the third layer is laminated with the first layer by transfer-coating.

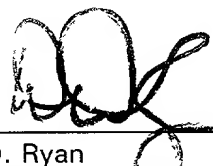
Serial No. Unknown
Preliminary Amendment

REMARKS

The foregoing Preliminary Amendment corrects dependency informalities found in certain of the claims as published during the International Phase.

Claims 1 through 4 and 21 through 35 are presented for prosecution. Favorable action is respectfully requested.

Respectfully submitted,

By 
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December 5, 2000

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FLEXIBLE SHEET MATERIAL AND METHOD
OF MAKING SAME

5 This invention is concerned with flexible sheet material and method of making same.

In caring for patients in hospital, pressure-sores (often called bed-sores and more correctly known as decubitus) are a potential problem. Additionally patients may also be incontinent or have exuding wounds. To try to protect patients from the risk of pressure-sores and prevent fluid transfer to the underlying mattress and any resulting cross-infection, various sheets or cover sheets have been introduced. Such protective sheets are, of necessity, impermeable to fluids microbes and pathogens. Moreover, to reduce the risk of pressure-sore development, the sheet needs also a certain amount of stretch, thereby reducing interface pressures on the patient's most vulnerable areas.

To this end, varying solutions have been proposed, including both "static" and "dynamic" systems. Whereas the static systems may operate as a sprung or foam block mattress with a cover sheet, the dynamic systems are inflatable and often consist of a series of cells, which are sequentially deflated so as to further reduce the interface pressure exerted on the various parts of the patient's body. Such mattresses have been successful in reducing the incidence of pressure sores and inhibiting their progression.

A further complication to this issue is that, as a result of the sheet cover being impermeable, the patient's skin can be in direct contact with

fluids, which can inhibit the healing process. For wounds (including pressure sores) to heal most effectively, they need to be exposed to a reasonable amount of air, and not left in contact with moisture.

5 In order for a material to be suitable for use as a protective mattress cover, it should preferably have the following properties: impermeability to liquid, good heat transmission, flexibility, resilience, stretch and recovery. This allows such materials to readily respond to the contours of the patient's body.

10

One of the various objects of the present invention is to provide a flexible sheet material through which air can be delivered.

Another of the various objects of the present invention is to provide
15 an improved flexible sheet material suitable for use as a mattress cover.

Another object of the present invention is to provide a flexible sheet material suitable for use as a patient-contacting sheet material to enable control of air transfer to regions of the sheet material which might come
20 into contact with a patient's body.

In one aspect the invention may be considered to provide a flexible sheet material comprising an air-permeable first layer and a second layer, the second layer being substantially air-impermeable but having a
25 controlled air permeability at a selected part of the second layer.

Preferably, the first and second layers are produced separately and the second layer (which is preferably of uniform thickness) is then laminated to the first layer. In a preferred sheet material in accordance

with the invention the second layer comprises an air-impermeable material having a set of perforations therethrough at the selected part.

Preferably, the first layer is a textile material, conveniently a relatively
5 extensible, flexible and resilient textile material; suitably the textile material is preferably knitted (but may be woven or a 'non-woven' provided that they have the necessary characteristics - stretch is specially important) and is a relatively open textile material with high loft to provide the desired air permeability characteristics.

10

Preferably, the second layer is a relatively extensible, flexible and resilient impermeable plastics material, suitably a polyurethane composition. Such compositions are typically polyester or polyether prepolymers extended by means of aliphatic or aromatic polyisocyanates
15 in combination with polyhydroxyl or polyamino compounds. The resulting elastomers may be applied as solutions, emulsions, in molten or prepolymerised forms. The second layer is preferably of uniform thickness, to minimise the risk of any thin regions being present in the second layer which may lead to unwanted leakage through the second
20 layer.

In a first sheet material in accordance with the invention the perforations may be of different dimensions in a first region of the selected part from those in a second region, the perforations in the first
25 region suitably being larger than those in the second region. Conveniently, the perforations in the first region each have a diameter between 0.2 mm and 1 mm and the perforations in the second region have a diameter between 0.1 mm and 6 mm.

The airflow through the perforated regions of the sheet material in accordance with the invention is preferably sufficient to give satisfactory ventilation.

5 In the first sheet material in accordance with the invention the first region of perforations extends lengthwise along a central part of the sheet material and the second region extends lengthwise at either side of the central part. Conveniently, the central part is between 25 cm and 35 cm in width preferably about 30 cm. Conveniently each part of the second
10 region at either side of the first region is between 7.5 cm and 15 cm wide, preferably about 10 cm. The combined width of the first and second regions is preferably between 40 cm and 65 cm, more preferably between 50 cm and 60 cm. In the first region the perforations are preferably between 0.1 and 1.6 mm in diameter, more preferably between 0.2 mm
15 and 1 mm. The perforations in the second region are preferably between 0.1 mm and 1.6 mm in diameter, more preferably between 0.1 and 0.6 mm.

Alternatively the perforations may all be of the same size, in which
20 case the perforations are preferably between 0.1 mm to 1.6 mm in diameter, more preferably between 0.6 to 1.2 mm.

The first sheet material in accordance with the invention comprises
a third layer on a face of the first layer opposite that carrying the second
25 layer, the third layer conveniently being formed separately from the first and second layers and laminated thereto. The third layer is air-impermeable and preferably of uniform thickness and in this first sheet material the first layer is permeable to air in a direction parallel to the surface of the sheet material as well as in a direction extending

transversely to the surface of the sheet material. Conveniently, the third layer is a polyurethane composition. Although polyurethane compositions are preferred for use as the second or third layers, other materials, for example PVC, synthetic rubber or acrylics, may prove suitable for use in materials in accordance with the inventions provided that they have the necessary characteristics.

A second sheet material in accordance with the invention merely comprises the first and second layers, no third layer being included. The perforations in the second layer range between 0.1 and 1.6 mm in diameter, more preferably between 0.1 and 1 mm in diameter.

Although the perforations described herein are generally circular, other shapes might be used provided that their areas are appropriate. Thus, if other shapes are used in materials otherwise similar to the first or second materials, their areas may correspond with the areas of the preferred circular perforations.

In another aspect the invention may be considered to provide a method of making a laminated sheet material comprising:-

- (a) procuring an air permeable first layer;
- (b) procuring an air-impermeable second layer comprising a material of uniform thickness;
- (c) laminating the first and second layers to one another to provide said laminated sheet material; and
- (d) forming a set of perforations through the second layer at a selected part thereof.

Preferably, in carrying out a method in accordance with the invention the first layer is a textile material, preferably a knitted textile fabric which is of open construction and high loft and is flexible, resilient and extensible. Preferably, the second layer is an impermeable plastic sheet material, suitably a polyurethane composition and is preferably flexible, extensible and resilient.

Preferably, the second layer is laminated with the first layer, more preferably by transfer coating but other laminating techniques may be used, eg. hot melt, adhesive spot techniques or pressure sensitive adhesive films. In transfer coating the second layer is formed by coating a support substrate, conveniently a release paper, with a layer of coating material of uniform thickness by any well known coating technique, the coating material conveniently being a polyurethane composition. The coating material is then cured or allowed to cure to form a flexible sheet of uniform thickness; more than one layer of coating material may be applied if desired. A thin adhesive (or tie) coat is then applied to the surface opposite the substrate and the first layer is brought into contact with the tie coat and pressed gently against it, thereafter being cured or allowed to cure to securely laminate the first layer and second layer to one another. Laminating by transfer coating avoids undue penetration of the first layer thus militating against undesirable reduction in flexibility or, extensibility resilience of the finished sheet material.

The perforations may be made by any suitable technique but are preferably made using a laser system after the first and second layers have been laminated to one another, the laser being chosen to perforate the second layer at selected positions but to not perforate or significantly affect the first layer. Although the perforations could be made whilst the

second layer is still supported by the substrate prior to being laminated with the first layer, that is not preferred.

In perforating the second layer, the perforations are chosen to be
5 such that the ratio of area of the perforations in the selected perforated part to the area of solid material in the selected part ranges between 1:5 cm² and 1:50 cm². However, the ratio of the area of the perforations to the area of the solid material of the selected part of the second layer may be varied according to the airflow which is desired through the
10 perforations.

In a method in accordance with the invention of making the first sheet material in accordance with the invention, a third layer is laminated to a face of the first layer opposite that to which the second layer is
15 laminated, preferably by transfer coating. The third layer is air-impermeable and of uniform thickness, to minimise the risk that unwanted leakage of air through the third layer may arise.

20 The second sheet material in accordance with the invention is produced by terminating the method after laminating the first and second layer and perforating the second layer.

Material in accordance with the invention may be used in the
25 manufacture of cover sheets for mattresses and for other purposes where it is desirable to supply a controlled flow of air to preselected locations. For example, material in accordance with the invention comprising three layers may be utilised in the manufacture of a body suit with the second layer on the inside, for treatment of patients suffering from hypothermia

where warm air may be supplied through the perforations to the interior of the suit.

There now follows a detailed description to be read with reference to the accompanying drawings of a flexible sheet material embodying the invention, and a method of making the sheet material likewise embodying the invention. It will be realised that the sheet material and methods have been selected for description to illustrate the invention by way of example. Although the second and third layers of a preferred sheet material in accordance with the invention are of uniform thickness with a set of perforations through the second layer at a selected part, other materials having controlled air permeability may be used. For example such materials (conveniently polyurethane compositions) may be made by coagulation techniques to form a microporous second layer, or other techniques for forming microporous sheet materials; such materials where construction permits, have characteristics similar to those referred to herein in respect of sheet material in accordance with the invention set out in Claim 1.

Irrespective of the manner in which the sheet material is rendered air permeable, to deliver a controlled air flow it is important to select suitable air transmission characteristics at the selected part of the material. Thus, for example, the air permeability should be sufficient to deliver a desired air flow rate eg. where the material is to be used to ventilate a patient.

Furthermore, where the material is to be used as a mattress cover the sheet material may be adapted to provide at least two lengthwise extending air permeable regions, a first region extending along a central part of the sheet material and a second (or further) regions at either side of the central

region; the central region conveniently has a greater air flow capacity than the second (or other) regions whereby to facilitate the ventilation of desired parts of the body of a patient supported on the sheet material.

5 Alternatively, when used as a mattress cover, the perforations may be arranged in an array centrally located relating to the mattress so as to correspond to that area which supports the torso region of a person lying on the mattress.

10 In the accompanying drawings:-

Figure 1 is a diagrammatic plan view showing a first sheet material embodying the invention; and

Figure 2 is a view of the first sheet material embodying the invention showing a perforated part of the material on a larger scale.

15 Figure 3 is a diagrammatic plan view of a further sheet material embodying the invention;

Figure 4 is a part sectional view taken along line IV-IV in Figure 3;

Figure 5 is a diagrammatic plan view of a strip of the sheet material shown in figure 3.

20 The first illustrative sheet material 10 is a flexible, resilient material and comprises an air permeable first layer 12 (see Figure 2). The first layer 12 is a loosely knitted high loft textile fabric which is relatively open in structure and is between 200 and 1000 micrometers in uncompressed thickness, more preferably between 200 and 600 micrometers and
25 conveniently about 400 micrometers; the thickness depends on the end use to which it is intended to put the material. The textile fabric which provides the first layer 12 is readily permeable to air considered in a direction parallel to the surface of the sheet material 10, as well as in a direction transverse to the sheet material 10.

The first layer 12 is laminated to a second layer 14 which is of uniform thickness but has a set of perforations 18, 20 extending through a selected part of the second layer 14. The selected part of the first sheet material 10 is indicated by dashed lines R which are parallel with opposite parallel edges 16 of the sheet material. The perforations 18, 20 are of different dimensions and are grouped in two regions. A first, central region lies between lines S parallel with the lines R and extends lengthwise along a central part of the sheet material 10; the perforation 20 are disposed in the first region. The perforations 18 are disposed in a second region which extends at either side of the first region lengthwise of the sheet material, the second region being disposed between one of the lines R and the adjacent line S. The perforations 20 in the first region are larger than those 18 in the second region and both sets of perforations are generally circular; however, the perforations may all have the same diameter or be of greater diameters according to the use to which the sheet material is to be put.

In the first illustrative sheet material the perforations 20 are preferably between 0.1 and 1.6 mm in diameter, more preferably between 0.2 and 1 mm in diameter. The perforations 18 are preferably also between 0.1 and 1.6 mm in diameter and more preferably between 0.1 and 0.6 mm in diameter.

The first illustrative sheet material further comprises a third layer 22 on the face of the layer 12 opposite the face carrying the second layer 14. The third layer is air-impermeable and provided by a polyurethane film of uniform thickness.

The second and third layers 14, 22 are conveniently of the same thickness (but may be of different thicknesses) preferably between 20 and 100 micrometers thick and more preferably between 20 and 60 micrometers thick, suitably about 40 micrometers.

5

In order to enable air to be introduced between layers 14, 22, the first illustrative sheet material further comprises larger openings 24 in marginal regions of the sheet material 10 adjacent the edges 16. The openings 24 conveniently are of about 30 mm diameter and the openings 10 24 in the second layer 14 may be provided by complete removal of the second layer 14 for the whole of the diameter of the opening 24 or by a series of closely adjacent holes within the boundary defining the opening 24.

15 The first illustrative sheet material 16 has an air impermeable seal along the opposite edges 16.

A second sheet material embodying the invention is generally similar to the first illustrative sheet material described above except that 20 the third layer 22 is omitted as are the openings 24 in the surface 14, and as is the impermeable seal along the edges 16, 26.

The first and second illustrative sheet materials are made by carrying out a method embodying the invention. In carrying out the first 25 illustrative method a suitable air permeable textile fibre fabric is procured to provide the first layer. The textile fibre fabric is conveniently supplied in a continuous length wound on a roll from which it is withdrawn to provide the first layer.

The second layer is made by coating a substrate with a layer of suitable polyurethane coating composition to provide on the substrate a polyurethane composition coating having a uniform thickness. The substrate is suitably a paper with a release surface. The substrate conveniently be supplied from a roll and the polyurethane coating coated onto the release surface by known coating techniques. The polyurethane coating is then cured to provide on the substrate a film of polyurethane of uniform thickness to form the second layer. If desired a plurality of separate polyurethane coatings may be applied to form a multi-coat second layer. The second layer is then coated with a thin tie coat which may be a further polyurethane composition (or other suitable adhesive eg. acrylic) but of much less thickness than the film which provides the second layer. Whilst the tie coat is still in a soft and tacky condition it is brought into engagement with the first layer and gently pressed thereagainst, the tie coat then being cured to laminate the second layer 14 to the first layer. This method of applying a surface coating to a substrate is commonly referred to as transfer coating. The first and second layers may be laminated together in this way to provide a continuous laminated sheet material.

In making the first illustrative sheet material, in carrying out this illustrative method, a third layer 22 provided by a polyurethane composition is applied to the first layer on the opposite face from that on which the second layer 14 is applied by a transfer coating technique, similar to that of the lamination of the first and second layers; the second layer 14 will, usually, have been separated from the support substrate prior to laminating with the third layer.

The perforations 18, 20 (and where appropriate openings 24) are preferably formed in the second layer after it has been laminated to the

first layer and has been separated from the release coat carried by the substrate on which the second layer is coated, but before the third layer is laminated on the opposite face of the first layer.

5 The second layer is perforated using a laser system which is able to perforate the second layer 14 at the required locations and with perforations of the required diameter, as the sheet material comprising the first and second layers is moved through the laser system operating simultaneously in line with the coating system (although this may be a
10 separate, remote operation, if required), in a continuous production technique (rather than a batch processing technique). A suitable laser system is available from the Spanish company MACSA under the trade name MAC2000 CO₂, which includes a CO₂ sealed laser having a wavelength of 10.6 micrometers. The same laser system may be used to
15 produce the openings 24 in the layer 14 where necessary .

If the second illustrative material is to be produced, provision of the openings 24 is not necessary and it is not necessary to laminate the third layer to the first layer 12.

20 Should the illustrative method be employed to produce the first illustrative material then it will be necessary to form the openings 24 and to laminate the third layer 22 to the first layer as outlined above.

25 In carrying out the illustrative method of making the first illustrative material it is necessary to form an air impermeable seal along the opposite lengthwise edges 16 of the sheet material produced and this can be done by any convenient means, for example ultrasonic welding or high frequency welding, use of an impermeable tape folded round the edge

and sealed to the second and third layers, heat sealing or any other suitable sealing system.

covers the width of the sheet material between the opposite edges 16 is conveniently between 85 and 150 cm, preferably between 85 cm and 120 cm. The region between the lines R in which the perforations are to be formed is suitably between 40 cm and 65 cm in width, preferably between 50 cm and 60 cm in width. Where openings 24 are formed in the second layer 14 they are conveniently closer to the perforated region R than the edges 16 of the fabric and the spacing between the openings is conveniently between 70 cm and 95 cm, preferably between 75 cm and 85 cm, depending on the width of the perforated region between the lines R.

Where one of the illustrative sheet materials is to be used as a cover for a mattress it is cut into discrete lengths, suitably between 140 cm and 360 cm in length and preferably between 210 cm and 250 cm in length.

For the first illustrative sheet material the transverse cut edges such as the edge 26 must be sealed together by any suitable means for example as used to seal the edges 16 in carrying out the illustrative method to create an airtight seal between the second and third layers. If desired the lengthwise edges 16 may also be sealed during manufacture of the cover instead of when making the first illustrative sheet material. For each such mattress cover there are conveniently five openings 24 along each side of the cover. Connecting means may be sealed to the layer 14 around the openings 24 to provide a supply of air under pressure to the openings 24.

In use of a cover comprising the first illustrative sheet material the cover is placed on a mattress with the second layer 14 uppermost and air under pressure is supplied to the openings 24. The air then permeates through the first layer between the second and third layers and the air escapes through any of the openings 18, 20 which are not completely closed by the patient's body. In mattress systems utilising pockets which are inflated sequentially, those of the perforations 18, 20 which are aligned with a deflated pocket will not be closed off by the patient's body which will be supported only by the inflated pockets and thus air can leak from the unclosed perforations 18, 20 to ventilate the exposed regions of the patient's body. When the previously deflated pockets are re-inflated the patient's body will be supported by the inflated pockets and the corresponding perforations 18, 20 will partially be closed by the patient's body but as others of the pockets deflate, those of the perforations 18, 20 corresponding with the deflated pockets will be open and ventilate the adjacent parts of a patient's body in this way. Thus, the whole of the patient's body can be ventilated in parts sequentially.

Because the air is supplied from edge regions of the covers formed from the first illustrative sheet material, there will tend to be an air pressure drop across the material from the edge regions towards the centre. The perforations 20 in the centre therefore are of larger diameter than those perforations 18 closer to the edges 16 to facilitate an even distribution of the air escaping from the perforations across the perforated region of the sheet material. If desired there can be perforations of several different diameters, the smallest diameter perforations being closest to the edges 16 and the perforations being of progressively larger diameter towards the centre of the sheet material. The sizes of the

perforations 18, 20 are chosen to provide the required air distribution in the use of the material.

5 The third layer of the first illustrative sheet material not only provides an air impermeable backing layer so that air introduced under pressure through the openings 24 is forced to escape through the perforations 18, 20 but also ensures that no body fluids leak through the cover sheet onto the underlying mattress, thus keeping the underlying mattress clean and sterile.

10

After use the cover sheet may be disposed of for hygiene reasons.

Although in the first illustrative sheet material, the openings 24 are provided in the second layer 14 for the introduction of air under pressure, 15 the openings for introduction of air under pressure could if more convenient, be formed in the third layer.

The second illustrative sheet material comprising only the first and second layers may be used in forming an inflatable mattress cover by 20 forming a cover of the second illustrative and sealing the cover sheet to an impermeable backing material around the lengthwise and transverse edges of the cover sheet to form an envelope with the second illustrative material forming one face. Air under pressure may then be introduced into the envelope formed between the cover sheet and the backing layer to inflate 25 the envelope, the air under pressure leaking gradually from the perforations 18, 20 to ventilate the body of a patient lying on the cover.

In this case, where the second illustrative sheet material forms one side of an inflatable envelope, the perforations 18, 20 may all be of the

same diameter or may vary in a manner similar to those of the first illustrative sheet material..

The region of the illustrative sheet material in which the perforations are formed are chosen to be of sufficient width to provide adequate ventilation to the bodies of patients who will lie on a cover sheet formed from the material.

Sheet materials generally similar to the illustrative materials can be used for purposes other than mattress covers as the sheet materials have an engineered permeability, the air permeability of the materials in accordance with the invention being able to be closely controlled in accordance with the end use requirements.

An alternative arrangement for introducing air in between layers 14, 22 is provided in the embodiment 70 illustrated in Figures 3 to 5.

In embodiment 70, a pair of longitudinally extending ducts 71 are preferably provided.

Preferably each duct 71 is formed by a longitudinal edge 12_a of the first layer 12 and a seal line 73 formed between layers 14, 22. Accordingly in between edge 12_a and a seal line 73 layers 14, 22 form an open space therebetween and so define a duct 71.

Air is introduced at one or both ends of each duct 71 and permeates into the fabric layer 12 from edge 12_a.

Preferably the layers 14, 22 are laminated together over the marginal region between seal line 73 and the adjacent edge 16. Preferably the marginal region has a width of about 50 mm.

- 5 Preferably the width of each duct 71 (ie the distance between edge 12a and seal line 73) is between 15 to 30 mm, more preferably between 20 to 25 mm.

10 The ducts 71 extend longitudinally of the sheet and so can conveniently be incorporated integrally with the sheet 70 during the manufacturing process as is illustrated in Figure 5 wherein a strip 76 of sheets 70 joined end to end are initially produced, the strip 76 being severed to form individual sheets 70.

- 15 In the illustrated embodiment 70, a pair of ducts 71 are provided. It will be appreciated that only one or more than two longitudinally extending ducts 71 may be provided.

20 In sheets 70, perforations 20 only are provided, preferably in an array 80 comprising columns 81 and rows 82. Preferably the array 80 covers an area centrally of the sheet 70 which corresponds to that area which will support the torso of a person lying on a mattress covered by sheet 70.

- 25 Preferably the array 80 has a length of between 900 to 1100 mm, and has a width of between 400 to 430 mm.

Preferably the array 80 comprises about nine rows 82, the spacing between adjacent rows 82 being about 120 mm.

The array 80 may comprise six columns 81, the spacing between adjacent columns 81 being about 85 mm.

- 5 Alternatively, the array 80 may comprise ten columns 81; the spacing between adjacent columns 81 being about 45 mm.

Preferably the perforations 20 defining the array 80 are of the same size, and preferably are between 0.1 mm to 1.6 mm in diameter, more
10 preferably between 0.6 to 1.2 mm.

Alternatively, it is envisaged that the array 80 may extend continuously for substantially the entire length of sheet 70. Alternatively, more than one array 80 may be provided for each sheet 70, the arrays 80
15 being spaced from one another in the longitudinal direction of the sheet 70.

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20CLAIMS

1. A flexible laminated sheet material comprising an air-permeable first layer, a second layer being substantially air-impermeable but having a controlled air permeability at a selected part of the second layer, the second layer being laminated to one face of the first layer, and a third layer laminated to the face of the first layer opposite that carrying the second layer, the third layer being air-impermeable and the first layer being permeable to air in a direction parallel to the surface of the sheet material and in a direction extending transversely to the surface of the sheet material to enable a desired air flow through the first layer for discharge through said selected parts of the second layer.
2. A sheet material according to Claim 1 wherein the second layer is of uniform thickness.
3. A sheet material according to Claim 2 wherein the second layer comprises an air-impermeable material having a set of perforations therethrough at the selected part.
4. A sheet material according to claim 3 wherein all the perforations are to the range of 0.1 mm to 1.6 mm in diameter, preferably 0.6 mm to 1.2 mm.
5. A sheet material according to any of Claims 1 to 4 wherein the first layer is a textile fabric.
6. A sheet material according to Claims 3, 4 or 5 wherein the second layer is a polyurethane composition.

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7. A sheet material according to Claim 3 wherein the selected part comprises a first region and a second region and wherein the perforations are of different dimensions in the first region from those in the second region.
8. A sheet material according to Claim 6 wherein the perforations in the first region are larger than those in the second region.
9. A sheet material according to Claim 8 wherein the perforations in the first and second region each have a diameter between 0.1 mm and 1.6 mm.
10. A sheet material according to Claim 9 wherein the first region extends lengthwise along a central part of the sheet material and the second region extends lengthwise at either side of the central part.
11. A sheet material according to any preceding claim wherein the third layer is a polyurethane composition.
12. A sheet material according to any preceding claim wherein one or more longitudinally extending ducts are provided between the second and third layers for ducting air under pressure to the first layer.
13. A sheet material according to any of Claims 1 to 11 comprising one or more openings in the second layer through which air under pressure can be supplied to the first layer.
14. A method of making a laminated sheet material comprising:-

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- (a) procuring an air permeable first layer;
- (b) laminating to one face of the first layer, an air-impermeable second layer comprising a material of uniform thickness;
- (c) laminating to the face of the first layer opposite to the face carrying the second layer, an air-impermeable third layer of uniform thickness; and
- (d) forming a set of perforations through the second layer at a selected part thereof.
15. A method according to Claim 14 wherein the first layer is a textile fabric.
16. A method according to either one of Claims 14 and 15 wherein the second layer is a polyurethane composition.
17. A method according to any one of Claims 14 to 16 wherein the perforations are made by perforating the second layer after the first and second layers have been laminated to one another.
18. A method according to any one of Claims 14 to 17 wherein the perforations in a first region of the selected part are of different dimensions from those in a second region.
19. A method according to any one of Claims 14 to 18 wherein the second layer is laminated with the first layer by transfer-coating.
20. A method according to any one of Claims 14 to 19 wherein the third layer is laminated with the first layer by transfer-coating.



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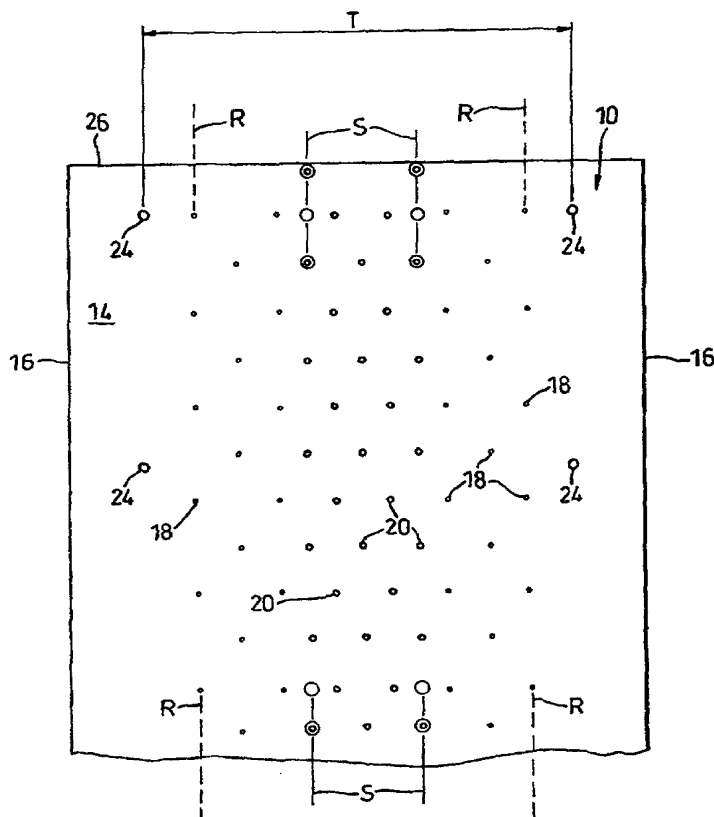
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(54) Title: FLEXIBLE SHEET MATERIAL AND METHOD OF MAKING SAME

(57) Abstract

A flexible, extensible, sheet material comprising an air-permeable first layer and a second layer, the second layer comprising an air-impermeable material of uniform thickness having a set of perforations therethrough at a selected part of the second layer. Conveniently, the material is made by a method of making a laminated sheet material comprising: (a) procuring an air permeable first layer; (b) procuring an air-impermeable second layer comprising a material of uniform thickness; (c) laminating the first and second layers to one another to provide said laminated sheet material; and (d) forming a set of perforations therethrough at a selected part of the second layer. The material may be used in protective covers for mattresses to provide ventilation of bodies of patients lying on the covers.



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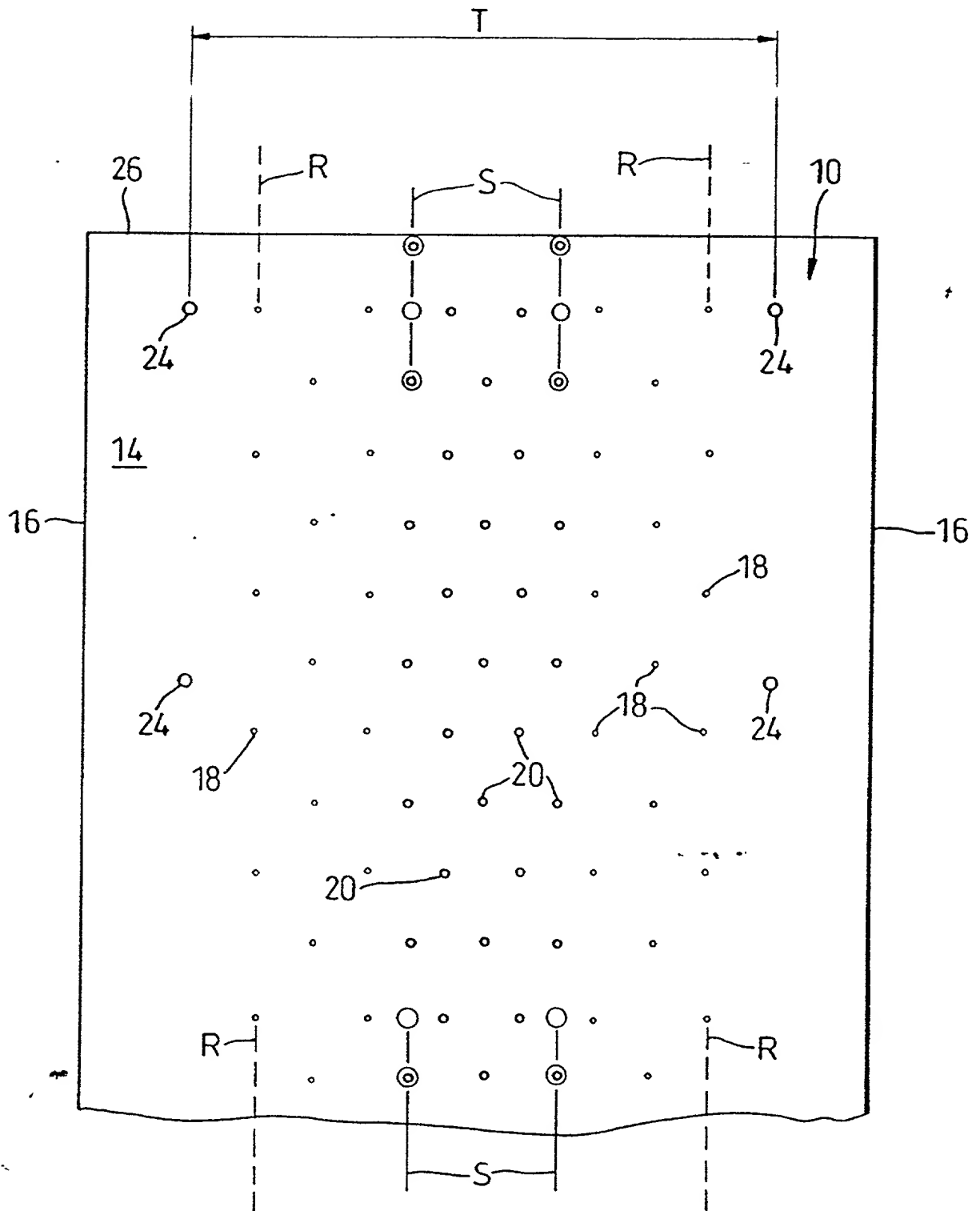
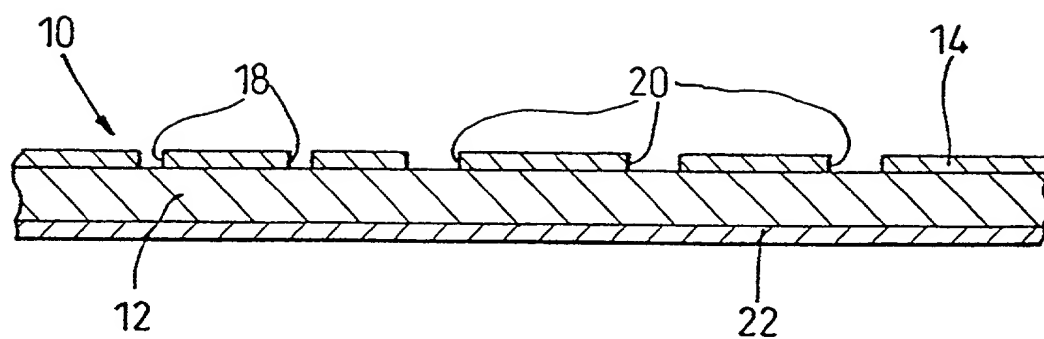


Fig. 1

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*Fig. 2*

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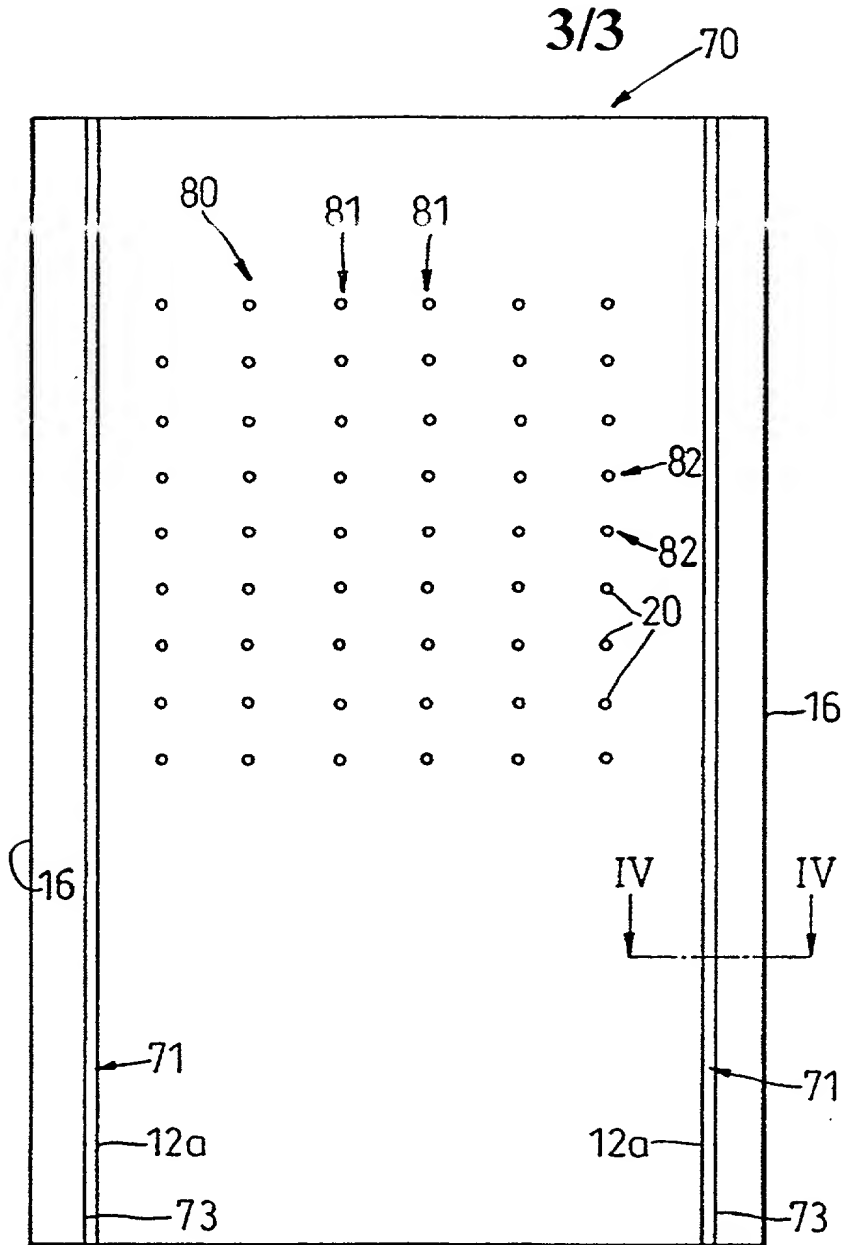


Fig. 3

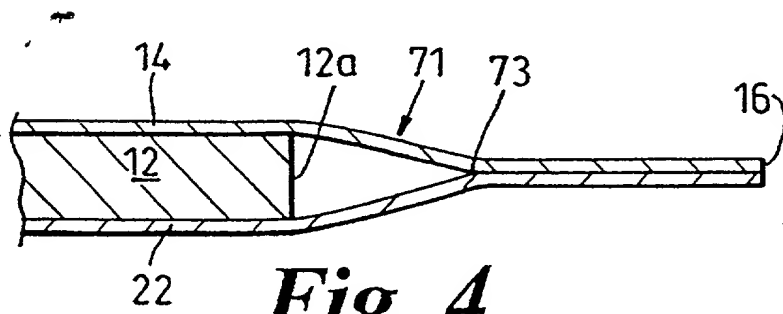


Fig. 4

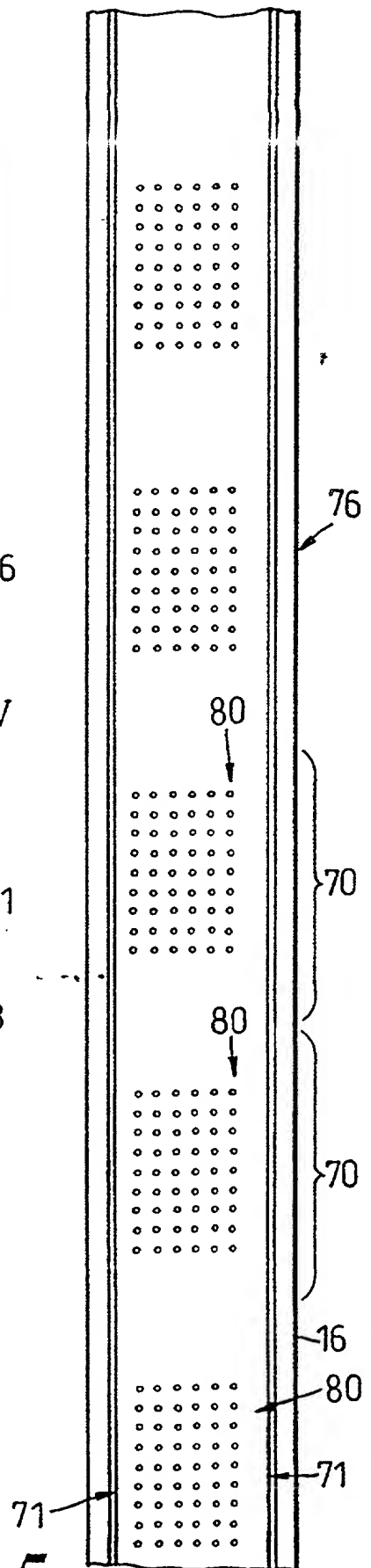


Fig. 5

Docket No.
9404.17285

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

FLEXIBLE SHEET MATERIAL AND METHOD OF MAKING SAME

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on (I.A. DATE) 04 JUNE 1999 as United States Application No. or PCT International Application Number USSN 09/701,948 (PCT/GB99/01756) and was amended on n/a

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

PCT/GB99/01756
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(Number)

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04/JUNE/1999
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(Day/Month/Year Filed)

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I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

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(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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